IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 1 CASES LISTED IN EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE CERTAIN OPINIONS OF DR. MARC TOGLIA

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs submit this Motion to Limit or Exclude Certain Opinions of Marc Toglia, M.D. ("Dr. Toglia"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Toglia is a sub-specialist in the field of Female Pelvic Medicine and Reconstructive Pelvic Surgery with a double board certification in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology, licensed in Pennsylvania.[1] He has been a paid consultant for Ethicon each year consecutively 1996 until at least 2013.[2] However, as an expert witness, Dr. Toglia offers opinions that far exceed his field of expertise, are unsupported by the required foundation, or are simply irrelevant to this litigation. This Motion seeks to exclude Dr. Toglia's opinions regarding the alleged safety and efficacy of Ethicon's TVT, Prolift, and Gynemesh PS devices, and various other opinions from all Wave I cases listed in Exhibit A.

[1] *See* Ex. B (Toglia TVT report) at 1 and attached CV; *see also* Ex. C (Toglia Prolift and Gynemesh PS report) at 1.
[2] *See* Ex. D, Deposition of Marc R. Toglia, M.D., dated October 2, 2015, 292:1-18; 295:8-297:23.

Dr. Toglia's reports offer sweeping, general opinions regarding the history of treatment of stress urinary incontinence and pelvic organ prolapse; the development and design of the products; the efficacy and safety of alternative devices and procedures; the qualities and properties of polypropylene and other synthetic graft materials; and the accuracy and adequacy of the Instructions for Use ("IFU").[3] Dr. Toglia's reports read more like a term papers, regurgitating cherry-picked data from studies that Dr. Toglia could not discuss on his own at deposition.[4] He was unable to provide meaningful insight on the studies despite being reminded that he could refer to any of his documents or his report at any time,[5] his statement that he was familiar with nearly all of the literature on his reliance list (and that most of it was already in his possession prior to working on this litigation),[6] and his claim that he has been reviewing data regarding devices such as the TVT since he before he began using them.[7] Dr. Toglia also relies heavily on his own clinical experience for his opinions. However, Dr. Toglia frequently contradicted the opinions contained in his expert report at deposition and was on numerous occasions unable to find even a single article to support his opinions. These contradictions and inability to cite to a single study on various topics demonstrate that he has offered these opinions without specialized knowledge of the subject and without utilizing a proper methodology as required by FED. R. EVID. 702.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of

[3] Ex. B at 1-30; Ex. C at 1-25.
[4] *Id.*
[5] Ex. D at 24:13-16.
[6] *Id.* at 31:12-24; 32:23-33:3.
[7] *Id.* at 342:6-11.

expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.[8] The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.[9]

ARGUMENT

Dr. Toglia's medical training in the fields of obstetrics/gynecology and female pelvic medicine does not automatically render his opinions on other ancillary issues admissible.[10] Indeed, to be admissible each individual opinion must satisfy the requirements of the Federal Rules of Evidence.[11] As a threshold matter, an expert witness "must have 'knowledge, skill, experience, training, or education' in the subject area in which he will testify."[12] In the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation."[13] Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*."[14] One of the most fundamental prerequisites to admission of an expert's opinion is that the opinion be related to that expert's specialized knowledge.[15]

Dr. Toglia's opinions must also be based upon reliable and proper methods.[16] As this Court has recognized:

> Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert

[8] *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).
[9] *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., v. Carmichael*, 526 U.S. 137, 141 (1999).
[10] *See Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001).
[11] *See, e.g., Gen. Elec. Co.*, 522 U.S. at 142; *see also Daubert*, 509 U.S. at 579.
[12] *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013) (quoting FED. R. EVID. 702).
[13] *Daubert*, 509 U.S. at 590.
[14] *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added).
[15] *See, e.g., U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995).
[16] *See Coleman v. Union Carbide Corp.*, 2013 U.S. Dist. LEXIS 140613, * 50 (S.D. W. Va. 2013) (holding that expert testimony must be reliable and relevant to be admissible).

> offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."[17]

The burden is on Ethicon to show that *each* of Dr. Toglia's opinions has a reliable foundation based on stated principles and methods.[18] Opinions not within Dr. Toglia's area of expertise or not the product of reliable principles and methods should be excluded.

There are no ascertainable "principles" or "methodology" in any of Dr. Toglia's opinions. Dr. Toglia merely regurgitates selected data from studies for his opinions in his report, as well as relies on his clinical experience which he has tracked using his "good memory" and "mental notes." Neither of these "methods" is sound and the resultant opinions should be excluded under FED. R. EVID. 702.

I. Dr. Toglia's Opinions are Duplicative, Unreliable, and Would Not Assist the Jury.

Dr. Toglia's opinions far exceed his qualifications, he was unable to support them at deposition with any literature or evidence, and his opinions based on his own clinical experience are admittedly based on speculation. His opinions should be barred as explained below.

A. Dr. Toglia's testimony regarding to his own clinical experience is unsupported by factual evidence.

Dr. Toglia repeatedly referred to his own clinical experience and teaching throughout his expert reports[19] and depositions.[20] Dr. Toglia specifically referenced his alleged high rates of patient follow up and low complication rate.[21] However, when asked how he arrived at these conclusions regarding his own clinical practice, Dr. Toglia alternated between relying on his

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[17] *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013).
[18] *See Daubert*, 509 U.S. at 597.
[19] Ex. B at 1-3, 21, 24-25, 28; see also, Ex. C at 3.
[20] Ex. D at 207:8-11, 64:12-14, 155:16-21, 162:1-11, 163:10-17 , 165:1-8, 172:18-173:10; *see also*, *See* Ex. E, Deposition of Marc R. Toglia, M.D., dated March 24, 2016, 47:24-48:13; 109:13-110:6; 138:13-21; 261:9-14
[21] Ex. D at 155:10-21, 156:21-157:5.

"good memory" or records and patient charts, which he stated were not readily available to him during his deposition. So essentially, Dr. Toglia is relying on his memory alone to account for the "thousands of gynecologic surgeries" he has performed, including "over 2,500 retropubic TVT's."[22]

For instance, when asked how he keeps track of the products he uses, Dr. Toglia responded, "I have a very good memory."[23] When pressed further, Dr. Toglia testified that to give an exact number, he would need to "go through some office records, some documentation elsewhere…."[24] Dr. Toglia also testified that he could not determine which complications occurred with the various products he has used or seen in his practice.[25]

Dr. Toglia stated that his patient follow-up rate for patients he implants with the TVT device is 90% or higher.[26] When asked for supporting documentation, Dr. Toglia responded that "[i]t is probably something that could be provided" and that someone would have to go through all the medical records in his practice on all his patients to support his claimed patient follow up rate.[27] But moments later Dr. Toglia contradicted his opinions by testifying that he has no follow-up data for patients who have left his practice or care.[28]

As to his teaching job, upon which he also bases his opinions, Dr. Toglia testified that he instructs residents on "really, basic training" and not training to "independently perform a procedure like an autologous fascial sling or Burch."[29] This does not satisfy Rule 702's most basic requirements: "If the witness is relying solely or primarily on experience, then the

[22] Ex. B at 2.
[23] Ex. D at 65:22-24.
[24] *Id*. at 66:1-67:23.
[25] *Id*. at 69:12-21 ("I would have to sit down and try and figure that out, counselor . . . ").
[26] *Id*. at 156:21-157:5.
[27] *Id*. at 161:18-162:10.
[28] *Id*. at 165:1-166:22.
[29] *Id*. at 218:21-5.

witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."[30] Dr. Toglia does not come even close to meeting that standard. He does not track his patients for mesh implantation or complications from mesh. Therefore, with no support or factual evidence, Dr. Toglia claims a high follow-up rate with a very low complication rate using the TVT device in his clinical practice. In other words, Dr. Toglia simply asks the Court to "take the expert's word for it."[31] The Court should conclude there is "too great an analytical gap" from his opinions.[32]

B. Dr. Toglia is unqualified to give opinions regarding the FDA and any related clinical testing

This Court has consistently excluded any mention of the FDA's 510(k) clearance for mesh products in all prior pelvic mesh cases.[33] The Court should rule similarly here. Dr. Toglia mentions the 510(k) clearance history in his report and testing submitted therewith[34]—but when questioned at deposition, Dr. Toglia conceded he only has a familiarity with the regulatory process and does not know the difference between "clearance" and "approval," as it applies to FDA actions.[35] Indeed, in his Gynemesh PS and Prolift report, he states that Gynemesh PS—which he concedes is a 510(k) cleared device[36]—"received FDA approval."[37] Similarly, Dr. Toglia could provide little, if any, information relating to Ethicon's "decision" to take Prolift off the market in response to the FDA's 522 study order—which he does not "consider [] to be

[30] *See* FED. R. EVID. 702 advisory note
[31] *Pugh v. Louisville Ladder, Inc*. 361 Fed. Appx. 448, 452 (4th Cir. 2010) (internal citations omitted).
[32] *Id.* at 454, fn.4
[33] *See Lewis v. Johnson & Johnson*, 991 F.Supp.2d 748 (S.D. W.Va. 2014); *Cisson v. Bard*, 2013 WL 3282926 (S.D. W. Va. 2013).
[34] Ex. B at 26.
[35] Ex. D at 408:18-409:14.
[36] Ex. C at 23.
[37] *Id.* at 9.

relevant to [his] generating [his] expert report."[38] Dr. Toglia should be precluded from testifying in any way regarding the FDA process, any related testing, or the FDA's enforcement or review of these products.

C. Dr. Toglia is not qualified to give opinions on polypropylene safety, durability, biocompatibility, MSDS and materials, and he has no reliable methodology to support those opinions.

Dr. Toglia opines in his reports that the type 1, macroporous, monofilament polypropylene used in Ethicon's devices has a long history demonstrating safety and efficacy, and is the "most highly compatible mesh there is."[39] However, when asked to opine on specific aspects of the polypropylene materials used in the devices, Dr. Toglia could not do so. He also testified that he is neither a chemical engineer[40] nor a biomechanical engineer.[41]

Dr. Toglia stated that he believed the TVT to be made of "lightweight" mesh but was unable to identify a single document that supported his opinion.[42] In fact, Dr. Toglia failed to show a basic understanding of what is meant by the terms "lightweight" and "heavyweight," despite opining on the effectiveness of "lightweight" meshes in his report[43] and citing to numerous published medical articles on his reliance list that describe the difference between the two *and state that Ethicon Prolene is in fact heavyweight polypropylene*.[44] Again, despite these

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[38] Ex. E at 129:6-133:5.
[39] Ex. B at 4-5; *see also* Ex. C at 22.
[40] Ex. E at 118:16-19.
[41] *Id*. at 123:25-124:2
[42] Ex. D at 55:14-58:3, stating that "everything that we are referencing in the report, the materials that we have included here today." supports his contention that the TVT is made of lightweight polypropylene; when asked to be more specific Dr. Toglia responded that "it would take hours to go over all of those things."
[43] Ex. B at 9, 25.
[44] *Id.* at 48 referencing Costello, C.R. Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient. (2007), *Id*. at 53 referencing Klein-Patel – paper 11 – Ultra-Lightweight synthetic mesh has similar cellular response but increased tissue ingrowth relative to heavier weight prototype; Female Pelvic Medicine & Reconstructive Surgery, Volume 17, number 5, Supplement 2, September/October 2011; *Id*., at 65 referencing Weyhe – Experimental comparison of

citations and opinions, Dr. Toglia testified that he doesn't "think that I could classify it based on weight, given the fact that it's a 1.1 centimeter strip of material." He went on to state that he doesn't "know that anybody would specifically state that the material was of a specific weight"[45] despite the fact that he cites to and opines on the clinical effects of mesh weight in his report and reliance lists.

Furthermore, Dr. Toglia did not know if the polypropylene material is the same polypropylene used in other pelvic products and that this was not part of his analysis.[46] Dr. Toglia testified he does not know what additives are added to polypropylene resin to make the Prolene mesh used in the devices, and he has never inquired as to what may be added.[47] Dr. Toglia does not have even a basic understanding of mesh classifications beyond the one article cited in his report and referenced at his deposition.[48] Dr. Toglia also contradicted himself by testifying that if deformation caused the TVT device to no longer fit his macroporous classification, he would not want to know because that is not "relevant."[49] And in his Gynemesh PS and Prolift deposition, he asserted that there was no definition or "cut-off" between lightweight and heavyweight mesh, or at least he could not determine the difference.[50] Simply put, these are not "expert" opinions.

Dr. Toglia also stated that the MSDS for the polypropylene used to make the TVT device was "regulatory paperwork" and "non-clinical,"[51] not relevant or reliable,[52] or even on the levels

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monofilament light and heavy polypropylene meshes: less weight does not mean less biological response; World J Surg (2006) 30: 1586-1591.

[45] Ex. D at 56:5-8.

[46] *Id*. at 54:1-55:5; see also Ex. E at 243:13-24.

[47] Ex. D at 144:16-146:8.

[48] Ex. B at ; Ex. C at 259:10-16.

[49] Ex. D at 260:9-19.

[50] Ex. E at 112:19-113:16.

[51] Ex. D at 238:4-24.

[52] *Id*. at 360:11-23.

of evidence to which Dr. Toglia would refer to form the basis of his expert opinions.[53] As established, Dr. Toglia is admittedly not qualified to opine on regulatory issues and therefore his opinions regarding the MSDS should be excluded.

Dr. Toglia's opinions regarding the polypropylene used in the devices at issue, their biocompatibility or durability, and the MSDS are not based on any reliable methodology or literature that Dr. Toglia can point to and should therefore be excluded.

D. Dr. Toglia is not qualified to testify about the complication rates and risks associated with the Burch and autologous fascial sling procedures and could not find a single study at his TVT deposition to support his claims.

Despite not using the Burch or autologous fascial sling procedures in his practice for at least the "last several years,"[54] Dr. Toglia opines on the efficacy and complications of these procedures in his TVT report[55] and during his deposition.[56] Dr. Toglia testified that with the Burch procedure, exposure of permanent suture in the vagina and bladder erosions are "one of the more common things that we see."[57] However, when asked at his TVT deposition to provide literature to support these opinions, Dr. Toglia could not do so. In fact it took almost ten minutes for Dr. Toglia to find a study that he believed supported his opinion regarding suture in the bladder with the Burch procedure.[58] However the referenced study referred to intraoperative passage of suture into the bladder—not the bladder erosions Dr. Toglia believed to be so "common."[59] Dr. Toglia then went off the record to continue his search of literature to support his opinions until finally admitting that he could find none.[60] As such, Dr. Toglia should not be

[53] *Id*. at 360:24-361:2.
[54] *Id*. at 217:2-120.
[55] Ex. B at 4-8, 10, 12, 15-19, 30.
[56] Ex. D at 114:22-124:19.
[57] *Id*. at 117:1-11.
[58] *Id*. at 120:3-121:18.
[59] *Id*. at 120:22-123:3.
[60] *Id*. at 123:7-124:19.

allowed to provide his unsupported and unreliable opinions about the complication rates and risks associated with the Burch and autologous fascial sling procedures.

E. Dr. Toglia relies on circular logic for his opinions regarding degradation and immunologic response, and cannot cite to reliable scientific evidence to support his opinions.

During his TVT deposition, Dr. Toglia vacillated between attempting to find literature to support his opinion that the polypropylene mesh in Defendant's devices does not degrade and declaring (on numerous occasions) that it does not matter if it degrades at all.[61] Despite opining that degradation is irrelevant to clinical outcomes, the only support he can muster for his opinion that degradation does not occur is to assert that a "lack of chronic problems suggests that there is no chemical degradation of the material"[62]—the *very thing* which he says will be unaffected by degradation. And when asked to point to literature supporting his opinion that degradation does not occur, Dr. Toglia cited a study by Falconer which examined biopsies of tissue, *not explanted mesh material*.[63] Dr. Toglia could cite to no other studies to support his degradation opinion. Moreover, Dr. Toglia has never looked at explanted mesh under a microscope[64]—so he cannot claim that his opinion is supported by his own observations or research.

The same situation occurred when Dr. Toglia attempted to find literature to support his opinion that there is no immunologic response to the devices. Dr. Toglia asked to go off the record to find his literature and could find no supporting evidence.[65] Dr. Toglia's opinions regarding degradation and the body's immunologic response to these polypropylene mesh devices are unsupported by any reliable scientific evidence, and therefore, must be excluded.

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[61] *Id*. at 140:9-13 ("what does it matter if the person is still continent? You know, it's not that are – we're suspending somebody form a bridge from this materials . . ."); 148:6-9 ("I would not want to know it [that the TVT device degrades] from Ethicon").
[62] *Id*. at 139:23-140:7.
[63] Ex. D at 137:2-138:22.
[64] *Id*. at 210:24-211:1; *see also* Ex. E 122:7-17.
[65] *Id*. at 198:16-201:23.

F. Dr. Toglia's opinions on the Instructions for Use ("IFU") and warnings are not based on a reliable methodology, and Dr. Toglia admitted that he does not understand parts of the TVT IFU.

Dr. Toglia opines that "[t]he IFU and Professional education for the [TVT and Prolift] are clear, useful and adequate to describe the procedure and potential risks."[66] Dr. Toglia clarified this opinion during his deposition; when asked if he believes that the TVT IFU is complete, he responded that he "believe[s] the instructions for use to be exactly that, they – they accurately describe the instructions on how the product is to be used. They provide step-by-step mechanics of the procedure."[67] However in response to the very next question—asking him if he thinks the TVT IFU provides a complete and accurate listing of all potential risks—he stated that he is "not sure what you mean by complete."[68] And when asked about a particular statement in the IFU regarding the TVT's alleged "bidirectional elastic property," Dr. Toglia responds that not only does he not know the basis for that statement, but that he cannot comment because he is unfamiliar with the context of that statement in the IFU.[69]

Dr. Toglia further reveals his lack of interest and understanding in warnings to patients and physicians by testifying that:

- "the only thing patients would want to know is whether or not the procedure worked long-term for them,"[70] and not that the device causes a chronic foreign body reaction;[71]
- He does not rely on Ethicon to provide him with information regarding the risk of chronic foreign body reaction[72] or chronic inflammation,[73] properties of the

[66] Ex. B at 17; Ex. C at 17.
[67] Ex. D at 280:2-9.
[68] *Id*. at 280:10-20.
[69] *Id*. at 284:20-285:23.
[70] *Id*. at 149:21-150:1.
[71] *Id*. at 125:22-153:1.

Prolene material that Ethicon felt were clinically important,[74] or management of patients;[75] and

- He cannot speak to what other doctors "might consider to be relevant," "might hold important," or "should or would want to know" in regards to the device;[76] and that whether doctors would want to know information about management of patients or the Prolene material is "beyond the scope of what I've prepared."[77]

This last statement—that he does not know what other physicians would want to know or need to be warned of—alone should preclude Dr. Toglia from offering opinions regarding the sufficiency of any IFU. Dr. Toglia's personal understanding of the risks and complications of the devices from his clinical practice is not, without more, sufficient to qualify him to make the broad assertion that all potential risks and complications were adequately warned of in the IFU.[78] As this Court held in *Tyree*, "without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice."[79] The Court should adopt a similar ruling and exclude Dr. Toglia's opinions regarding the IFUs and the sufficiency of any warnings (or lack thereof) to physicians and patients. These opinions are, as Dr. Toglia points out, "beyond the scope" of his own testimony, understanding, and preparation.

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[72] *Id*. at 152:10-20.
[73] Ex. B at 13-21.
[74] Ex. D at 245:13-21; 247:20-248:5.
[75] *Id*. at 248:1-5.
[76] *Id*. at 256:1-4; 261:1-5; 269:13-17.
[77] *Id*. at 248:7-12.
[78] *See Tyree*, 2014 U.S. Dist. LEXIS 155138 at *184.
[79] *Id*. at *184-86.

CONCLUSION

For the foregoing reasons, Dr. Toglia's opinions do not meet the requirements for admission under *Daubert* and FED. R. EVID. 702, 403 and 104. Accordingly, his opinions in this case must be excluded, or at least limited.

Dated: April 21, 016

By: /s/ Edward A. Wallace

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Edward A. Wallace